EPA Office of Research and Development (ORD)
Research Terms and Conditions
(November 2020)

Environmental Protection Agency Home Page
EPA Grants Information
EPA Research Grants
OMB Uniform Guidance

The EPA research terms and conditions apply to research grants and cooperative agreements awarded by the Office of Research and Development. The research terms and conditions do not apply to conferences, training projects, fellowships, or awards made as part of the People, Prosperity, and the Planet (P3) program.

EPA implementation of the research terms and conditions includes the applicable EPA general terms and conditions available at: https://www.epa.gov/grants/grant-terms-and-conditions.

1. Technical Reporting

As a result of this agreement, the recipient agrees to provide to EPA's Office of Research and Development (ORD) annual progress reports with associated summaries, and a final report with an executive summary along with a copy of any papers resulting from the research conducted.

A. Annual Progress Reports

The recipient agrees to submit annual progress reports to the EPA Project Officer within 90 calendar days after the end of each reporting period. If the agreement was partially funded, so that an additional increment of funding is to be provided, EPA may elect to not provide further funding until the recipient has submitted the required annual progress report. EPA may withhold payment if progress reports are not submitted by the due date. In addition, if EPA determines that the recipient has not made sufficient progress toward completing its research, EPA may terminate the assistance agreement. Sufficient progress is demonstrated by the grantee meeting the project schedule and milestones described in the approved research plan to the maximum extent practicable, while taking into account any extenuating factors that may have delayed progress. The reporting period begins at the project start date, or, for subsequent years, on the annual anniversary of the start date. The reports should generally not exceed five 81/2" X 11" pages, exclusive of the summary discussed below. These reports shall include:

(1) Brief statements covering work status, work progress, preliminary data, results, and evaluations made during the reporting period, including a comparison of actual accomplishments with the goals and objectives (outputs/outcomes) for the period. Address difficulties you have encountered (or might encounter) in carrying out this project and remedial actions (to be) taken. If the goals of the project have not changed from the original

application, state this. If these have been modified, provide the revised goals and discuss the reason for the modification. Discuss any problems, delays, or adverse conditions which may materially impair the ability to meet the results (outputs/outcomes) specified in the application. If the work includes human subjects research, provide the status of required approvals [Institutional Review Board (IRB) and EPA Human Subjects Research Review Official (HSRRO) final approval]. Where appropriate, provide the date the annual IRB approval materials and/or approved IRB amendment materials were sent to the Project Officer.

(2) A discussion of any absence or changes of key personnel involved in the project.

(3) A discussion of expenditures to date along with an explanation of any costs which are significantly higher or lower than originally estimated. Revised budget information will be required under this agreement if any significant changes in the size or scope of the project or in the originally-negotiated total estimated costs are anticipated for the project period.

(4) Statements addressing how the quality assurance requirements of 2 CFR 1500.12 and the agreement are being met, especially focusing on the system in place that assures the quality of environmental measurements, data generation and use.

(5) Results (outputs/outcomes) to date, emphasizing findings and their significance to the field, their relationship to the general goals of the award, their relevance to the Agency's mission, and their potential practical applications.

(6) A discussion of subaward monitoring activities under 2 CFR 200.332(d). Examples of items that must be reported if the information is available are: 1. Summaries of results of reviews of financial and programmatic reports. 2. Summaries of findings from site visits and/or desk reviews to ensure effective subrecipient performance. 3. Environmental results the subrecipient achieved. 4. Summaries of audit findings and related pass-through entity management decisions. 5. Actions the pass-through entity has taken to correct deficiencies such as those specified at 2 CFR 200.332(e), 2 CFR 200.208 and 2 CFR 200.339 Remedies for Noncompliance.

(7) Assurance that research misconduct has not occurred during the reporting period. EPA defines research misconduct as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results [65 FR 76262.1], or ordering, advising or suggesting that subordinates engage in research misconduct.

(8) Planned activity for the subsequent reporting period, including a description of equipment, techniques, and materials to be used or evaluated. If the work includes human subjects research, provide information on upcoming IRB approvals/renewals/amendments and any materials to be submitted for EPA HSRRO review.

(9) Publications arising from this project. Copies of publications and reprints which have not previously been submitted to the Agency should be enclosed with the report.
The publication list should be cumulative of previous Annual Reports.

(10) In addition, the recipient agrees to submit Annual Report Summaries with each annual progress report for posting on the Internet. These will be placed on EPA/ORD website(s). EPA will not alter the content of a summary without consultation with the Principal Investigator(s). The summary should be submitted in the following format:

EPA Assistance Agreement Annual Report Summary (1-2 pages)
Period Covered by the Report:
Date of Report:
EPA Assistance Agreement Number/FAIN:
Title:
Investigators:
Institution:
Research Category:
Period of Performance:
Objective of Research:
Progress Summary/Accomplishments (Outputs/Outcomes):
Publications/Presentations:
Future Activities:
Supplemental Keywords:
Relevant Websites:

B. Final Report.

The recipient agrees to submit a final report to the EPA Project Officer (PO) within 120 calendar days after the expiration of the project period. The Project Officer may require clarifications of the final report before the report is considered acceptable. Although there are no page restrictions on the final report (other than on the executive summary below), EPA does not expect a final report of great length. However, this document shall include a discussion of:

(1) Project activities over the entire period of funding, describing the recipient's achievements with respect to the stated project goals and objectives (outputs/outcomes).

(2) Complete details of all technical aspects of the project--both negative and positive--the recipient's findings, conclusions, and results, including the associated quality assurance results.

(3) An evaluation of (a) the technical effectiveness and economic feasibility of the methods or techniques investigated or demonstrated, if applicable and (b) an explanation of how the research adds to the understanding of or solutions for environmental problems or is otherwise of benefit to the environment and human health. This discussion should be a minimum of one paragraph long and written in terms understandable by the educated layman.

(4) A discussion of subaward monitoring activities under 2 CFR 200.332(d). Examples of items that must be reported if the information is available are: 1. Summaries of results of reviews of financial and programmatic reports. 2. Summaries of findings from site visits and/or desk reviews to ensure effective subrecipient performance. 3. Environmental results

the subrecipient achieved. 4. Summaries of audit findings and related pass-through entity management decisions. 5. Actions the pass-through entity has taken to correct deficiencies such as those specified at 2 CFR 200.332(e), 2 CFR 200.208 and 2 CFR 200.339 Remedies for Noncompliance.

(4) Publications arising from this project. Copies of publications and reprints which have not previously been submitted to the Agency should be enclosed with the report. The publication list should be cumulative of previous Annual Reports.

(5) In addition, the recipient agrees to submit an Executive Summary with the final report for posting on the Internet. This will be placed on EPA/ORD website(s) along with a list of publications. EPA will not alter the content of a summary without consultation with the Principal Investigator(s). Note: the recipient need not create this summary if the final report is ten pages or less, and is suitable for inclusion in the EPA website. The summary should be submitted in the following format:

EPA Assistance Agreement Final Report Executive Summary (3-5 pages)
Period Covered by the Report:
Date of Final Report:
EPA Agreement Number/FAIN:
Title:
Investigators:
Institution:
Research Category:
Project Period:
Objective of Research:
Summary of Findings (Outputs/Outcomes):
Publications/Presentations:
Supplemental Keywords: (do not duplicate terms used in Progress summary)
Relevant Websites:

C. Form of Reports

The recipient agrees to provide final and annual reports and associated summaries in an electronic format. The electronic versions shall be submitted in PC format, using commonly available word processing software or PDF. When requested by the Project Officer, these reports shall also be submitted in hardcopy format.

2. Other Recipient Responsibilities

A. Annual Meeting Attendance.

The Principal Investigator(s) will attend annual EPA Research Grants Seminars (otherwise known as progress reviews or All-Investigators Meetings) if requested by EPA, to present and discuss the project. Per EPA instructions, expenses for travel to these meetings have been provided within the funding for this agreement.

B. Publications and/or Other Public Release of Results

1. The grant recipient agrees that any reports, documents, publications or other publicly available materials supported by this assistance agreement shall contain the following statement:

"This publication [article] was developed under Assistance Agreement No._____ awarded by the U.S. Environmental Protection Agency to [name of recipient]. It has not been formally reviewed by EPA. The views expressed in this document are solely those of [name of recipient or names of authors] and do not necessarily reflect those of the Agency. EPA does not endorse any products or commercial services mentioned in this publication."

The Lead/Contact principal investigator is responsible for ensuring that all members of the project team comply with these acknowledgement requirements.

2. Additionally, the above acknowledgement language should be included in any presentations, posters, websites, and media interviews.

3. The recipient is strongly encouraged to continue to notify the Project Officer of any papers that are published based on the research under the agreement. EPA intends to post references to all publications resulting from the agreement on the EPA website.

4. The recipient agrees to submit one copy of each peer reviewed journal article(s) resulting from this research, in addition to the final technical report.

C. Extensions

Subject to the limitations in 2 CFR 200.308, without prior written approval from EPA the recipient may initiate a one-time no-cost extension of this project of up to 12 months by notifying EPA in writing, with the supporting reasons and revised project period end date, at least ten calendar days before the project period end date specified in the award agreement. Notwithstanding 2 CFR 200.308, if the extension causes the project period to exceed five years or is in addition to a previously requested one-time no-cost extension of this project, the extension should be requested at least 120 calendar days in advance of the project period end date and approved by EPA. These approvals are necessary due to EPA Office of Research and Development policy.

D. Foreign Travel

No foreign travel will be funded by this agreement without prior written approval of the EPA. The recipient agrees to notify the EPA Project Officer at least 60 days before any

proposed foreign travel to allow the EPA sufficient time to obtain the appropriate clearances. The recipient understands that funds awarded under this assistance agreement may not be used for international activities unless prior written notification is received from the EPA Project Officer that the international activities have been approved by EPA's Office of International and Tribal Affairs. For purposes of this condition, international activities include any foreign travel paid for with EPA funds. In addition, the recipient understands that all foreign travel must comply with the Fly America Act. All travel must be on U.S. air carriers certificated under 49 U.S.C. Section 1371, to the extent that service by such carriers is available even if foreign air carrier costs are less than the American Carrier.

E. Publications and Data Access Assistance Agreement Terms and Conditions

The following Assistance Agreement Terms and Conditions pertain to public access to journal publications, associated author manuscripts, and the associated underlying digital research data and metadata resulting from research funded wholly or in part by an EPA assistance agreement. If the recipient's assistance agreement supports scientific research as defined in EPA's Policy for Increasing Access to Results of EPA-Funded Extramural Scientific Research, the recipient agrees to comply with the applicable provisions of the policy described in these terms and conditions. EPA's Policy for Increasing Access to Results of EPA-Funded Extramural Scientific Research may be accessed at: https://www.epa.gov/research/non-epa-researcher-requirements.

1. The recipient is responsible for ensuring the journal publication or the author manuscript associated with the journal publication is deposited into the National Institutes of Health's PubMed Central (PMC). When a journal does not submit a journal publication or author manuscript associated with the journal publication directly to PMC, the recipient agrees to make the author manuscript associated with the journal publication accessible to the public at no charge via PMC. Journal publications or author manuscripts associated with the publications must be posted in PMC no later than the end of the embargo period of twelve months after journal publication. The National Institutes of Health Manuscript Submission (NIHMS) system is the manuscript submission system for all materials deposited in PMC and as such will be used for all submissions of extramural scientific research journal publications and author manuscripts associated with the journal publications. Instructions for using the NIHMS system may be found at: https://www.epa.gov/research/non-epa-researcher-requirements. EPA retains the right to require recipients to provide author manuscripts to EPA upon acceptance of the manuscript for publication.

2. The recipient agrees to notify the EPA Project Officer within 30 days of the date a journal publication or author manuscript associated with a journal publication is deposited in PMC. The recipient is responsible for providing EPA with notice of all deposits of journal

publications resulting from this assistance agreement, regardless of whether deposits are made by indexed journals.

3. Recipients may request to extend the twelve month embargo period for a specific scientific field by demonstrating that this requirement is inconsistent with the objectives articulated in Office of Science and Technology Policy's (OSTP) memorandum entitled "Increasing Access to the Results of Federally Funded Research." Requests should be submitted to the EPA Project Officer.

4. Extramural researchers are required to obtain an Open Researcher and Contributor id (ORCID id). An ORCID id provides a persistent digital identifier that distinguishes a researcher from every other researcher and, through integration in key research workflows such as manuscript and grant submission, supports automated linkages between the researcher and his/her professional activities ensuring that the researcher's work is recognized. Researchers can apply for and use an ORCID id free of charge by registering at: https://orcid.org/register.

5. Extramural researchers are responsible for creating and maintaining My National Center for Biotechnology Information (NCBI) accounts and NIHMS accounts for manuscript submission purposes. Both accounts are free to use. Researchers can register for a My NCBI account at: https://www.ncbi.nlm.nih.gov/account/register/?back_url=&partners-uri=cms:/account/partners.

6. The recipient agrees to post scientific research data underlying a journal publication to a publicly accessible data repository within 30 days of the date the journal publication or associated author manuscript becomes accessible to the public, whether made accessible by the journal at the time of publication or by PMC following the embargo period, unless: (a) the dataset has already been made accessible to the public via public release or another sharing mechanism; or (b) the research data cannot be released due to one or more constraints, such as requirements to protect personal privacy, proprietary interest, property rights, national security, or dual use research of concern.

Data must be accessible in at least one machine-readable format, preferably a widely-used or open-standard format and should also be accompanied by machine-readable documentation (metadata), preferably based on widely-used or international standards. Regardless of the format used, datasets must contain enough information to allow independent use (understanding, validation and analysis) of the data. All data and derived products that are used to support the conclusions of a peer-reviewed journal publication must be made accessible in a form that permits verification and reproducibility of the results. Further, data

should undergo quality review before they are made publicly accessible to safeguard against the release of personally identifiable or proprietary data.

7. The recipient agrees to notify the EPA Project Officer when, and to what location, the scientific research data underlying a journal publication are posted. Notification is also required when the scientific research data underlying a journal publication are not made publicly accessible. The recipient agrees to notify the EPA Project Officer within 30 days of the date the scientific research data underlying a journal publication resulting from this assistance agreement are posted to a publicly accessible data repository. In instances where the data are not made publicly accessible, the recipient agrees to notify the EPA Project Officer within 30 days of the date the decision is made to not make the data publicly accessible along with the reason(s) for not making said data accessible.

8. When a journal does not submit the metadata record for the journal publication or author manuscript associated with the journal publication to PMC via NIHMS entry, the recipient agrees to enter the metadata record for the associated author manuscript via NIHMS entry when the manuscript is submitted to NIHMS.

9. The recipient agrees to provide the metadata record for the dataset underlying the journal publication via EPA's dataset metadata repository within 30 days of the date the journal publication or associated author manuscript becomes accessible to the public, whether made accessible by the journal at the time of publication or by PMC following the embargo period. The interface for providing dataset metadata to EPA's dataset metadata repository is accessible at: https://edg.epa.gov/epa-open-data-metadata-editor/. Guidance for providing dataset metadata to EPA's dataset metadata repository are accessible at: https://www.epa.gov/research/non-epa- researcher-requirements.

10. The recipient agrees to notify the EPA Project Officer within 30 days of the date a journal publication or associated author manuscript's metadata record is uploaded to PMC. In addition, the recipient agrees to notify the EPA Project Officer within 30 days of the date the metadata for the dataset underlying a journal publication is uploaded to EPA's dataset metadata repository.

11. When an assistance agreement supports a joint publication with an EPA researcher, if the journal does not submit the journal publication or associated author manuscript and associated metadata to PMC via NIHMS entry, the EPA researcher will be responsible for ensuring the author manuscript associated with the journal publication is posted in PMC and the author manuscript's metadata record is provided via NIHMS entry displayed through PMC.

12. Data collected may be subject to several laws and regulations regarding information privacy, including the Health Insurance Portability and Accountability Act (HIPAA) and the Common Rule (EPA-funded research, 40 CFR Part 26). All applicable laws and regulations must be followed when handling personally identifiable information (PII). While EPA has not issued guidance for de-identifying PII, we suggest that researchers follow the guidance provided by the Department of Health and Human Services related to the de-identification of protected health information (PHI) under the HIPAA Privacy Rule. This provides two ways to de-identify information – the "safe harbor" method and the "expert" method. Both methods are discussed in detail at: https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de- identification/index.html.

- The safe harbor method relies on the dataset being stripped of a set of 18 types of identifiers [45 CFR 164.514(b)(2)], at which point the data are no longer considered to be PHI.
- The expert method relies on consultation with an expert who uses scientific/statistical principles to evaluate the likelihood of accidental release of the PII, and who determines that the risk of the information being used on its own or in conjunction with other available data poses a very small risk.

Under the Common Rule regulations, which apply to research involving human subjects that was conducted or supported by EPA, one of the criteria for approval of research requires that protections for privacy and confidentiality are adequate [40 CFR 26.111(a)(7)]. Thus, the study protocol that was approved by an Institutional Review Board (IRB) and the EPA Human Subjects Research Review Official (HSRRO) should have included methods that would be used to protect the information obtained from or about subjects, including PII. These methods should be consulted and followed to protect the privacy of subjects and maintain the confidentiality of data as part of that research. In scenarios involving secondary analysis of existing data, if the PII obtained for the original purpose was de-identified, any research involving only that de- identified information would not involve human subjects and thus would not be subject to the Common Rule requirements. This is the functional equivalent of the "safe harbor" method described above, and the same principles would apply to public access datasets.

13. If the Scientific Data Management Plan (SDMP) changes during the conduct of the research (e.g., SDMP originally indicated scientific research data would not be generated), the recipient must obtain EPA approval of the revised SDMP. The SDMP must describe the revisions associated with the items (i.-ix.) listed below:

i. Types of scientific research data and metadata to be generated and/or collected under the award.
ii. The location where the data will be publicly accessible.

iii. The standards to be used for data and metadata format and content.
iv. Policies for accessing and sharing the data including provisions for appropriate protection of privacy, security, intellectual property, and other rights or requirements consistent with applicable laws, regulations, rules, and policies.
v. Plans for digital data storage, archiving, and long-term preservation that address the relative value of long-term preservation and access along with the associated costs and administrative burden.
vi. A description of how data accessibility and preservation will enable validation of published results or how such results could be validated if data are not shared or preserved.
vii. Roles and responsibilities for ensuring SDMP implementation and management (including contingency plans in case key personnel leave the project).
viii. Resources and capabilities (equipment, connections, systems, software, expertise, etc.) requested in the research application that are needed to meet the stated goals for sharing and preservation (reference can be made to the relevant section of the research application's budget justification).
ix. If appropriate, an explanation as to why data sharing and/or preservation are not possible.

14. The recipient must provide outputs and/or deliverables developed under this assistance agreement. This includes providing: (1) electronic copies of journal publications or the author manuscripts associated with the journal publications; (2) weblinks to the locations where the scientific research data underlying the journal publications are publicly posted; (3) weblinks to the metadata records for the journal publications or associated author manuscripts; and (4) weblinks to the metadata records for the scientific research data underlying the journal publications. The recipient will report on the status of publications and research data creation, collection and preservation, including any deviation from the approved SDMP required by this assistance agreement in their progress reports and final report. The reports must describe the publications and datasets developed under this assistance agreement. The recipient must provide the following information associated with each journal publication developed during the reporting period in their progress report with a summary of all journal publications and datasets developed under the award in their final report.

(a) Title of journal article
(b) Author
(c) Journal name
(d) Date of journal article publication
(e) Journal article digital object identifier (DOI) (e.g., CrossRef)
(f) Are EPA-funded data associated with the article?
(g) Are the data publicly accessible?

(h) URL or DOI for the associated data
(i) Date the data were made publicly accessible
(j) Title of the dataset
(k) Description of the data
(l) Date of submission of publication or associated author manuscript to NIHMS
(m) NIHMSID
(n) PMCID/PMID

15. Unless authorized by the EPA, failing or delaying making a journal publication or associated author manuscript resulting from EPA-funded extramural research, as well as the scientific research data underlying the journal publication or associated author manuscript, accessible to the public in accordance with the submitted Scientific Data Management Plan (SDMP), may be considered by EPA when making future award decisions.

16. Recipients must not sign agreements with publishers that restrict EPA's license rights under 2 CFR 200.315 or the requirement to deposit publications or associated author manuscripts in PMC.

17. Recipients are responsible for ensuring these publication/data access conditions are also met by subrecipients and contractors.